

## **Remarks**

### **Claim status**

Following Applicants' response filed January 30, 2009 (filed in response to an Office Communication mailed January 14, 2009) and previous responses to Restriction Requirements, claims 42-49 were pending and claims 42-44, 47, and 49 read on the species elected for initial examination. The Examiner withdrew claims 46, 46, 48, and 49 and examined claims 42-44 and 47 in the Office Action mailed April 13, 2009.

Claim 42 is amended by the present amendment to recite that the polypeptide does not comprise full length chlorotoxin, to recite an objective of the method, and to correct an inadvertent typographical error in the word "histidine". No new matter is introduced by these amendments.

Applicants respectfully request rejoinder of claim 49 on the basis that no legitimate basis was provided for withdrawing claim 49, which reads on embodiments in which polypeptides are labeled. The Examiner remarked that "Applicants have argued that claim 49 encompasses the peptide TTDHQMARKS; however applicants have declined to identify any label, and none is apparent." Applicants respectfully point out that the recited sequence "TTDHQMARKS" is an amino acid sequence. Those of ordinary skill in the art would appreciate that a label may be attached to an amino acid residue, or may be otherwise associated with a peptide, without changing the "sequence" of the amino acids in the peptide. To give but one example, radioactive labels (as are well known in the art and are also specifically discussed and exemplified in the specification), do not alter amino acid sequences. Thus, the present claims encompass peptides with the amino acid sequence TTDQHMARKS (as well as other peptides comprising the sequence  $TTX_1X_2X_3MX_4X_5K$  as set forth in the claims), whether or not they are labeled. Thus, there is no need, nor any requirement, to identify a label within the polypeptide TTDHQMARKS.

### **Rejection under 35 U.S.C. § 112, first paragraph – enablement**

Claims 42-44 and 47 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

In levying this rejection, the Examiner has remarked that “the claims are drawn to a method, yet no objective of the method is recited. As such, all objectives are encompassed.” Applicants respectfully submit that these remarks are irrelevant to a proper analysis of patentability under section 112. The present claims are methods claims reciting particular steps. The relevant analysis is whether the steps themselves satisfy the requirements of section 112. There is no requirement that an objective be recited. The Examiner has not presented any challenge to the enablement of the *steps* recited in the present claims. Rather, he has noted that these particular steps can be practiced in different contexts (*e.g.*, contacting cells *in vitro* vs *in vivo*). That the same steps might be practiced for different *reasons* and/or in different *contexts* does not affect the analysis of whether those steps are *enabled*.

Regardless, solely in order to advance prosecution of the present application, Applicants have amended claim 42 to recite an objective: “such that specific binding is achieved.” Thus, an objective of the claimed methods has been clearly stated.

The Examiner has made conclusory statements that, for example, “the vast majority of embodiments (that are encompassed) lack enablement,” and “Clearly, ‘undue experimentation’ would be required to practice even a small fraction of the embodiments that are encompassed”. Yet, Applicants do not find the Examiner’s conclusion to be “clear” at all. Performance of the claimed method requires:

(1) provision of the recited polypeptide; the Examiner does not challenge that the specification provides sufficient guidance for those of ordinary skill to obtain the peptide; and

(2) contacting the polypeptide with one or more cells under conditions that permit specific binding of the polypeptide to the cells such that specific binding of the polypeptide to the cells is achieved; the Examiner does not challenge that the specification provides extensive discussion, and indeed exemplification of such contacting, resulting in binding. For example, Examples 1, 2, 9, and 12 exemplify contacting and specific binding to glioblastoma cells *in vitro*; Examples 3 and 11 exemplifies contacting and specific binding in prostate cancer cells *in vitro*; and Examples 4-6 exemplify contacting and specific binding to glioblastoma cells *in vivo*.

Applicant respectfully points out that the present invention provides new *compositions* (i.e., new *polypeptides*) that are related to chlorotoxin. Those of ordinary skill in the art are well familiar with methods of contacting chlorotoxin with cells to achieve specific binding; that knowledge is applicable to the presently provided polypeptides and cannot be ignored.

Although he mentions *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) in the Office Action, and lists the Wands factors, the Examiner provides no specific analysis of why any particular *Wands* factors are not met for the present claims. Applicants cannot provide any specific response when no specific argument or analysis is provided.

For all these reasons, Applicants respectfully request that this rejection be withdrawn.

#### Rejection under 35 U.S.C. § 103(a)

Claims 42-44 and 47 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Soroceanu *et al.* (1998), which discloses use of full length chlorotoxin to target primary brain tumors. Soroceanu *et al.* does not disclose polypeptides comprising chlorotoxin subunits but not comprising full length chlorotoxin, nor does Soroceanu *et al.* disclose methods of contacting cells with such polypeptides. Without acquiescing to Examiner's interpretation of claim 42 as previously presented, Applicants note that claim 42 has now been amended to recite that "the polypeptide does not comprise full length chlorotoxin". Therefore, claim 42 and its dependents (which includes claims 43-49) are patentable over Soroceanu *et al.* Furthermore, there is no teaching or suggestion in Soroceanu *et al.*, of the particular chlorotoxin fragments or derivatives recited in the present claims; Soroceanu *et al.* simply cannot anticipate or render obvious the claimed invention.

Applicants respectfully request removal of this rejection.

It is believed that Applicants have fully paid all fees due with this response. In the event that any additional fees are due, please charge any fees that are associated with

this matter and *necessary* to ensure pendency of the present application and/or to protect the priority date of this application, or credit any overpayments, to our Deposit Account No. 03-1721. No authorization is provided to charge *optional* fees (*e.g.*, claims fees); should the PTO be of the view that additional fees are required, a Notice to that effect is respectfully requested.

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Respectfully submitted,  
/Brenda Herschbach Jarrell, Ph.D./  
Brenda Herschbach Jarrell, Ph.D.  
Reg. No.: 39,223

CHOATE, HALL & STEWART LLP  
Patent Group  
Two International Place  
Boston, MA 02110

bjarrell@choate.com  
Tel: 617-248-5175  
Fax: 617-248-4000